by weight per total weight of the pharmaceutically acceptable base, respectively.--

REMARKS

Claims 1-17 are pending in this application. Claims 9-10 have been canceled. Claim 17 has been added. Support for new claim 17 can be found on page 3, lines 11-19. Claims 1-7 and 3-16 have been amended. Support for the amendments to claims 1-7 can be found on page 3, line 20 to page 4, line 1, and support for the amendments to claims 12, 14 and 16 can be found on page 3, lines 1-3. No new matter has been added.

Rejection under 35 USC § 112, first paragraph

The Examiner rejects claims 14-16 under the first paragraph of 35 USC § 112 because the Specification does not provide enablement for 1-menthanol. This was a typographical error. Claims 14 and 16 have been amended to recite l-menthol. Withdrawal of the objection and reconsideration of the claims is respectfully requested.

Rejection under 35 USC § 101

The Examiner rejects claims 9 and 10. Claims 9 and 10 have been canceled.

Rejection under 35 USC § 112, second paragraph

The Examiner rejects claims 9 and 10 as being indefinite for failing to recite the steps involved in the method. Claims 9 and 10 have been canceled.

The Examiner rejects claims 4-8 and 14-16 for being indefinite for use of the term "a high molecular weight compound", which the Examiner says is a relative term. Applicants respectfully traverse the rejection.

The term "a high molecular weight compound", and similar terms, are often used in this field and is understandable by one skilled the art. In fact, the Examiner has cited two patents, Noda et al., U.S. Patent 5,519,046 and Block et al., U.S. Patent 6,090,403, that use similar language to claim and describe the compositions of those inventions. In claim 1 of Noda et al. (column 10, line 22), Noda claims a "fomentation . . . of at least one water soluble high-molecular substance" and Block et al. (column 6, lines 36-39) describes "a thickener that helps the ointment set" that is "a high molecular weight natural or synthetic polymer."

In this field, such terms are often used and understandable for the person in this field. Further, the high molecular weight compound used in the present invention is used as a part of a base. The Specification at page 3, line 20 to page 5, line 2 discloses the bases and hydrophilic high-molecular weight compounds contemplated by the present invention. Respectfully, Applicants

request withdrawal of the rejection and reconsideration of the claims. N9

Rejection under 35 USC § 102 (b)

Yoshida et al., U.S. Patent 4,205,685

The Examiner has rejected claims 1 and 3-13 as being anticipated by Yoshida et al., U.S. Pat. 4,205,685. The Examiner indicates that, "Yoshida et al. teach a wet pack (patch) composition comprising gelatin and sorbitol and further comprising menthol and peppermint oil (column 4, line 57 bridging to column 5, line 10). Method of use such as for headache are recited in column 11, lines 50-66." Applicants respectfully traverse the rejection.

The present invention discloses and claims a migraine-alleviating drug composition consisting of l-menthol and one or more essential oils as active ingredients in a pharmaceutically base. Yoshida et al. discloses and claims a thermogenic sheet-combined poultice. The object of the invention of Yoshida et al.'s patent is to form a simplified and highly effective thermogenic sheet combined poultice. This thermogenic sheet combined poultice consists of two portions, namely a thermogenic sheet and a poultice containing a wet pack. The wet pack of the thermogenic sheet combined poultice is not required to contain medicine. (See column

4, lines 31-37, and Examples 7-9.) Thus, unlike the present invention, the invention is not intended for use as a drug.

In the event the wet pack portion of the thermogenice sheet combined poultice contains medicine, Yoshida et al. discloses the various medicines (which must be heat-stable) that may be used in the wet pack (column 4, line 62-column 5, line 2). In the examples of Yoshida et al., a wet pack composition containing menthol, camphor, methyl salicylate, thymol and peppermint oil (Examples 1-3 and 5-6), and a wet pack composition containing only methyl salicylate (Example 4) are shown for preparing a thermogenic sheet combined poultice. The wet pack composition does not meet the limitation of the present invention. Specifically, in one example, the wet pack composition contains camphor, which cannot be a component of the present drug composition, and in another example, it contains only methyl salicylate but does not contain l-menthol, which is a required active ingredient of the present drug composition.

Furthermore, Yoshida et al. is directed to heat therapy using the thermogenic sheet combined poultice, and the methods of use of the thermogenic combined poultice recited in column 11, lines 50-66, is a general list. A person using the thermogenic combined poultice would expect relief due to the heat. The examples using the wet pack with a medicinal fluid do not include treatment of headache. The activity of the wet pack in Yoshida et al. is

silent. (See Table 8 in column 17). Yoshida does not teach use of a wet pack to relieve a headache.

Yoshida et al. is directed to heat therapy using the thermogenic sheet combined poultice. The wet pack composition disclosed in Yoshida et al. does not indicate the use of l-menthol and one or more essential oils as active ingredients in a pharmaceutically acceptably base to alleviate migraine headaches. Yoshida et al. does not teach the present invention. Withdrawal of the rejection and reconsideration of claims 1, 3-8 and 3-13 is respectfully requested.

Noda et al., US Patent 5,519,046A

The Examiner has rejected claims 1 and 3-7 as being anticipated by Noda et al. The Examiner indicates that Noda et al. teaches a patch composition comprising high-molecular weight substances combined with humectants and water and that l-menthol and peppermint oil and other essential oils are incorporated in such composition. Applicants respectfully traverse the rejection.

Noda et al. discloses a composition containing at least ketorolac as an active ingredient. The present invention discloses and claims a migraine-alleviating drug composition consisting of l-menthol and one or more essential oils as active ingredients in a pharmaceutically base. Noda et al. does not teach l-menthol and peppermint oil as active ingredients for alleviating a migraine.

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In Noda et al., l-menthol and peppermint are used as absorption promoters of keterolac (column 3, lines 38-39). intended use argument

The composition taught and claimed in Noda et al. and that taught and claimed in the present invention are different. Noda et al. does not anticipate claims 1 and 3-7. Applicants respectfully request withdrawal of the rejection and reconsideration of claims 1 and 3-7.

Block et al., US Pat. 6,090,403A

The Examiner has rejected claims 1-8 and 14-16 as being anticipated by Block et al. The Examiner indicates that Block et al. teach a patch and an ointment comprising a menthol, a polymeric gum and a polyhydric alcohol and that oil of peppermint along with the menthol is recited in claims 2, 9, and 16. The Examiner also states, "[a]lthough the compositions of Block et al. are for congestion instead of migraine headache, the intended use must result in a structural difference between claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the compositions of the patent are capable of performing the intended use of soothing a migraine headache, then it meets the claim."

The present invention discloses and claims a migraine-alleviating drug composition consisting of l-menthol and one or more essential oils as active ingredients in a pharmaceutically

base. Block et al. discloses and claims a skin patch containing a symptomatic cold reliever dispersed in an ointment. The symptomatic cold reliever of Block et al. can be selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra, coltsfoot, ginger and naphazoline hydrochloride. This group does not teach that the active ingredients must be 1-menthol and one or more essential oils.

Your Claims do not include

Block teaches that one preferred embodiment of the ointment contains camphor, menthol, eucalyptus oil, spirits of turpentine, a humectant and a thickener (column 7, line 62 to column 8, line 7) and another preferred embodiment of the ointment contains camphor, menthol, eucalyptus oil, spirits of turpentine, glycerine, aloe vera and a thickener (column 8, lines 32-34). These preferred embodiments contain components other than the active ingredients (1-menthol and one or more essential oils) and a pharmaceutically accepted base disclosed in the present invention. Block et al. does not disclose an external migraine-alleviating drug consisting simply of 1-menthol and an essential oil as active ingredients.

The composition taught and claimed in Block et al. and that taught and claimed in the present invention are different. Block et al. does not anticipate claims 1-8 and 14-16. Applicants respectfully request withdrawal of the rejection and reconsideration of claims 1-8 and 14-16.

35 USC § 103 (a)

The Examiner has rejected claims 1-16 as being unpatentable over Barr et al. U.S. Pat. No. 6,197,823 B1. The Examiner indicates, "Barr et al. teach topical composition (column 7, lines 5-17) comprising menthyl lauryl pidolate of which menthol is the active component and acts as an analgesic in an amount of from 0.1% to 16% menthol in the formulation (column 5, lines 16-19)" and that lavender flower oil or lavender oil (column 5 lines 65-66) can be added to the composition. The Examiner indicates that Barr et al. also discloses methods of using the composition, including relief of arthritis pain, neuropathy, post surgical scarring and hemorrhoidal pain but not migraine headaches. The Examiner states that, "[I]t would have been obvious to have treated a migraine headache with the compositions of Barr et al. since they are taught to be useful for treatment of pain resulting from, inter alia, arthritis. One of skill in the art would have been motivated to administer the compositions of Barr et al. to treat a migraine

headache because they are well known to treat pain." Applicants respectfully traverse the rejection.

Barr et al. discloses and claims a composition that contains capsaicin. Although capsaicin is known to effectively relieve pain, it is also known to be a potent skin irritant that burns the skin (column 1, line 56 to column 2, line 12). Barr et al. relates to a composition containing a capsaicin based pain reliever that does not burn when applied topically or when exposed to sunlight or water (column 2, lines 28-30). To eliminate the burning, Barr et al. includes a carrier and an encapsulation agent in the composition (column 3, lines 60-65 and column 4, lines 32-53).

The composition disclosed and claimed in Barr et al. also contains esters of amino acids. Barr et al. states that the preferred esters are menthyl and lauryl esters of amino acid. The most preferred embodiment is menthyl lauryl pidolate, for which menthol is the active component and acts as an analgesic (column 5, lines 8-17). However, menthol itself is not used as an ingredient in the composition.

The composition of Barr et al. is significantly distinct from the present invention. Barr et al. does not disclose the use of menthol and an essential oil as the active ingredients to relieve pain. Barr et al. specifically uses capsaicin as the active ingredient. Barr et al. also added other components (an encapsulation agent and a light diffusing compound) to make the

do not exclude

composition less irritating to the skin and more effective in pain relief. It would not have been obvious to a person skilled in the art to take the teachings of Barr et al. to arrive at the present invention.

As the components of the present invention are different from the ingredients of Barr et al., claims 1-16 are unobvious in light of Barr et al. Withdrawal of the rejection of claims 1-16 and reconsideration of the claims is respectfully requested.

CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Jaconda Wagner (Reg. No. 42,207) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Attached hereto is a marked-up version of the changes made to the application by this Amendment.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), applicant(s) hereby petition(s) for an extension of time for one (1) month(s) for filing a reply to the Office Action dated October 30, 2001 in connection with the above-identified application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 9-10 have been canceled.

The claims have been amended as follows:

1. (Amended) [An external] A migraine-alleviating drug composition suitable for [a local] external application, comprising:

active ingredients consisting of 1-menthol and [an] one or more essential [oil as active ingredients] oils; and

a pharmaceutically acceptable base.

2. (Amended) The drug composition claimed in claim 1, wherein the [external] migraine-alleviating drug [for a local application] composition is an ointment.

3. (Twice Amended) The drug composition claimed in claim 1, wherein the [external] migraine-alleviating drug composition is a patch.

4. (Amended) The drug composition claimed in claim 1, wherein the [external] migraine-alleviating drug [for a local application] is in a patch prepared by mixing 1-menthol and [an] one or more essential [oil] oils as active ingredients into a base containing a hydrophilic high-molecular weight compound, a

polyhydric alcohol and water.

5. (Amended) The patch claimed in claim 4, wherein the essential oil is [at least one essential oil] selected from the group consisting of lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil.

6. (Amended) The patch claimed in claim 4, wherein the amounts of 1-menthol and [the] one or more essential [oil] oils are 0.01-1% by weight per total weight of the pharmaceutically acceptable base and 0.001-1% by weight per total weight of the pharmaceutically acceptable base, respectively.

7. (Amended) The patch claimed in claim 4, wherein the amounts of a hydrophilic high-molecular weight compound, a polyhydric alcohol and water are 2-20% by weight per total weight of the pharmaceutically acceptable base, 8-60% by weight per total weight of the pharmaceutically acceptable base and 20-80% by weight per total weight of the pharmaceutically acceptable base, respectively.

11. (Amended) A [therapeutic] method for alleviating migraine [by dermally administrating] comprising the step of: administering to a patient in need thereof a drug composition

containing as active ingredients 1-menthol and [an] one or more essential [oil] oils in a pharmaceutically acceptable base in an effective amount to [the] said patient; and

said drug composition is administered dermally.

12. (Amended) The method claimed in claim 11, wherein the drug composition is a patch or an ointment.

13. (Amended) The method claimed in claim 11, wherein an application region of the drug composition is face, forehead, nape of the neck or temple.

14. (Amended) The drug composition claimed in claim 1, wherein the [external] migraine-alleviating drug composition [for a local application] is in an ointment prepared by mixing [1-methanol] 1-menthol and [an] one or more essential [oil] oils as active ingredients into a pharmaceutically acceptable base containing a hydrophilic high-molecular weight compound, a polyhydric alcohol and water.

15. (Amended) The ointment claimed in claim [15] 14, wherein the essential oil is [at least one essential oil] selected from the group consisting of lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil.

16. (Amended) The ointment claimed in claim [15] 14, wherein the amounts of [1-methanol] 1-menthol and the essential oil are 0.01-1% by weight per total weight of the pharmaceutically acceptable base and 0.001-1% by weight per total weight of the pharmaceutically acceptable base, respectively.

Claim 17 has been added.